UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

MEMORANDUM

5/11/2020

SUBJECT: Product Chemistry Review for **HM 4005 Antimicrobial** EPA Reg. No.: **83019-3**

FROM: Joseph Williams Jr.
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THRU: Karen P. Hicks, Team Leader 05/14/2020
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TO: Eric Miederhoff, PM Team 31 / Karen Leavy
Regulatory Management Branch I
Antimicrobials Division (7510P)

Registrant: Gelest Biosystems, LLC
Action code: A570
Agency Due Date: 5/20/2020
DP No.: 456047
Submission No.: 1045009
E-Sub No.: N/A
Classification: EP
Process: Nonintegrated system
Pesticide type: Antimicrobial

MRID(s):51036501, 51036502

Formulation from label			
PC code(s)	CAS #(s)	Active Ingredient(s)	% weight
107403	199111-50-7	3-(trihydroxysilyl)propyldimetyloctadecyl ammonium chloride	5%
		Other Ingredients	95%
		Total	100%

I. BACKGROUND

The Registrant, Gelest Biosystems, LLC, has submitted data to support a new manufacturing process for their product: HM 4005 Antimicrobial EPA Reg. No. 83019-3.

II. RELEVANT DOCUMENTS

	RECEIVED	N/A
REFERENCED: CSF BASIC *,* (2/18/2010)	--	
Comments**:**		

III. FINDINGS

a. Product Formulation:

	TGAI	MUP	EUP	Food use	Non-food use
Non-integrated	☐	☐	☒	☐	☒
Integrated	☐	☐	☐		

Active Ingredients(s)	Nominal	Upper limit	Lower limit
1-Octadecanaaminum,N,N-dimethyl-N-[3-(trihydroxysilyl)propyl],chloride	5	5.5	4.5
	YES	**NO**	**N/A**
1. The certified limits of all ingredients are within 40 CFR standard certified limits.	☒	☐	☐
2. Wider certified limits were requested and rationale was accepted.	☐	☐	☒
3. The nominal concentration(s) of the active ingredient is in agreement with the label.	☒	☐	☐
4. The chemical IDs and analytical information for density, pH, and flammability are consistent with Series 830 Group B data.	☒	☐	☐
5. All inert ingredients are approved for non-food use pesticide formulations.	☒	☐	☐
6. The impurities present >0.1% are identified.	☐	☐	☒
7. Impurities of toxicological significance have an upper certified limit.	☐	☐	☒

b. Product Label:

	Yes	**NO**	**N/A**
The formula contains one of the following:			
1. 10% or more of petroleum distillate	☐	☐	☒
2. 1.0% or more of methyl alcohol	☐	☐	☒
3. Sodium nitrite at any level	☐	☐	☒

4. A toxic list 1 inert at any level	☐	☐	☒
5. Arsenic in any form	☐	☐	☒
6. If yes to 1-5, then the inert ingredient list contains a relevant footnote	☐	☐	☒
7. Appropriate warning statements regarding flammability or explosive characteristics of the product are included on the label	☐	☐	☒
8. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.	☐	☐	☒
9. The product requires an expiration date at which time the nominal concentration falls below the lower certified limit.	☐	☐	☒

IV. Additional Findings

- Although Guideline 830.1650 Description of Formulation Process is acceptable, it should be noted that instructions for the formulation process do not specify the actual ingredients to be used in the process. Instead the company has provided a general process that should be followed which used the ingredients and the amounts of the ingredients listed on the approved CSF.

V. Conclusion

The Product Science Branch of Antimicrobials Division finds the proposed Guideline 830.1650 Description of Formulation Process and data submitted for Guideline 830.1700 Preliminary Analysis **acceptable for** *HM 4005 Antimicrobial* EPA Reg. No. 83019-3.

VI. Table A:
Series 830 guidelines – Group A

OPPTS#	Name	Status	MRID
830.1650	Description of formulation process	Acceptable	51036501
830.1700	Preliminary analysis	Acceptable	51036502